UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANT ETHICON, INC.'S MOTION AND INCORPORATED MEMORANDUM OF LAW SUPPORTING ENTRY OF A PROTECTIVE ORDER PROHIBITING PLAINTIFFS FROM SEEKING ANY FURTHER PRODUCTION OF OUS MATERIALS

INTRODUCTION

Pursuant to the Court's Pretrial Order #56 [doc. no. 671], Ethicon, Inc. ("Ethicon") respectfully asks the Court to issue a protective order barring plaintiffs from seeking additional non-U.S. documents ("OUS" documents) in this litigation.

Ethicon has already produced a million and a half pages of OUS materials, including regulatory documents. Even though plaintiffs have not shown any legitimate need for the materials they already have, they now want more of the same. If Ethicon were required to comply with plaintiffs' request for all foreign regulatory documents, that global effort, involving 67 countries, would cost the Company between $500,000 and $1 million. At some point, the Court must say to plaintiffs, "Enough is enough." Because the only purpose served by additional foreign discovery in this litigation would be harassment, that time has now come.[1]

[1] In Pretrial Order #56, the Court also ordered the parties to brief any discovery disputes regarding patents and hernia mesh documents. Plaintiffs have requested patent applications (Request No. 37) and

BACKGROUND

To date, Ethicon has produced over 9.5 million pages of documents in this litigation from more than 290 custodians and at least 136 central sources. More than 250,000 of those documents – nearly 1.6 million pages – are from the custodial files of approximately 52 OUS custodians and other sources. (*See* 4-23-13 Correspondence from B. Watson, Ex. 1 hereto; June 2, 2013 Declaration of Pamela Downs ("Downs 6/2/13Decl.") ¶ 13, Dkt. No. 632-4.) Ethicon has also produced relevant documents from numerous OUS central sources and databases, including Norderstedt ACMS Agile (as well as Neuchatel Agile), EU Clinical Research Data Entry Group Share, EU Health Care Compliance Group Share, UK 522 Order Group Share, UK TMF Paper Files, and UK Trial Master File Group Share. [2] (*Id.*) In addition, Ethicon has produced the worldwide adverse event information for the products at issue. (August 2, 2013 Declaration of Pamela Downs ("Downs 8/2/13 Decl. ¶ 13) ¶ 13, Ex. 2 hereto.)

During the meet-and-confer process concerning the production of OUS documents, plaintiffs requested regulatory documents from three countries: Japan, France and Australia. Even though the regulatory processes in those countries differ from those of the United States and are irrelevant to this litigation, Ethicon nevertheless agreed to collect and produce the requested documents from the three countries plaintiffs selected. Doing so required Ethicon to

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agreements relating to patents for pelvic mesh products (Request No. 27), and Ethicon has agreed to produce these documents to the extent they have not already been produced. (*See* Correspondence from B. Watson, Ex. 1 hereto). Accordingly, the patent issue appears to be resolved. The parties continue to meet and confer concerning the production of hernia mesh documents and appear to be headed toward a resolution. If they are unable to resolve their differences on this point, Ethicon will seek a protective order from the Court in a future motion.

[2] Documents produced from the Norderstedt ACMS Agile and Neuchatel Agile databases consist of manufacturing process documents. Documents produced from the EU Clinical Research Data Entry Group Share, UK TMF Paper Files and the UK Trial Master File Group Share consist of clinical study documents maintained in the EU. The EU Health Care Compliance Group Share contains documents related to EMEA Marketing, and the UK 522 Order Group Share contains documents related to the 522 order and product decommercialization.

work with individuals in each of the countries to locate and collect responsive documents. In addition, Ethicon was required to translate a significant number of documents from France and Japan. (*See* Downs 8/2/13 Decl. ¶ 13.) Responsive, non-privileged regulatory documents from these three countries have been produced to plaintiffs.

Plaintiffs also requested that Ethicon produce marketing materials for the products at issue from 32 separate countries. Despite the breadth of this request, and even though marketing materials are generally stored in the country of origin, making the collection logistically complicated, Ethicon agreed to this request too. To date, Ethicon has produced the unique marketing materials that it has been able to locate for these 32 foreign countries. (*See* Downs 6/2/13 Decl. ¶ 18.)[3]

In addition to producing this significant amount of document discovery, Ethicon also offered in January to produce a Rule 30(b)(6) witness to testify about the location and storage of OUS documents and the burden of producing more of these materials to the plaintiffs. The purpose of this deposition was to allow an informed dialogue concerning the feasibility of additional OUS discovery. Although Ethicon immediately began to prepare its witness for this deposition, counsel for plaintiffs did not serve a 30(b)(6) deposition notice until March 2, 2013. (*See* 4-23-2013 Letter from B. Watson, Ex. 1 hereto.) After counsel for Ethicon reviewed the 41 topics and 98 subtopics in the notice, Ethicon offered to make the witness available the week of April 8, 2013 (*see* 3-4-13 D. Jacobs letter, Ex. 3 hereto) but plaintiffs' counsel did not respond. Counsel for Ethicon subsequently sent several additional letters to plaintiffs' counsel in the following months in an attempt to schedule the 30(b)(6) deposition (*see* 3-21-13 W. Gage Letter,

[3] Ethicon produced these marketing materials, although nothing suggests that they would have reached any plaintiff or her physician. Of the thousands of plaintiffs with claims pending in this MDL, fewer than 10 were implanted outside the United States.

Ex. 4 hereto; 4-1-13 B. Watson Letter, Ex. 5 hereto; 4-23-13 B. Watson Letter, Ex. 1 hereto), but each time counsel received no response.

After ignoring all of Ethicon's attempts to resolve the OUS discovery issues for months, plaintiffs filed a motion to compel on May 9, 2013, asking the Court to order Ethicon to produce "all" OUS documents related to pelvic mesh products. At the hearing on that motion, plaintiffs' counsel clarified this request, indicating that plaintiffs seek any OUS documents that involve "testing, manufacturing, design and regulatory" issues.[4] The enormous scope of this discovery cannot be overstated. It would involve separate document searches in 67 countries around the globe, in numerous languages, many of which would have to be translated before they could be reviewed for production. Plaintiffs have been unable to explain why they need these documents, many of which would be duplicative of the documents already produced from Japan, France and Australia.

ARGUMENT

The federal "discovery rules are not a ticket to an unlimited, never-ending exploration of every conceivable matter that captures an attorney's interest." *Evans v. United States*, No. 10 C 1929, 2011 U.S. Dist. LEXIS 9371, at *3-4 (N.D. Ill. Jan. 26, 2011). While the parties "are entitled to a reasonable opportunity to investigate the facts," discovery, "like all matters of procedure, has ultimate and necessary boundaries. Discovery has limits and these limits grow more formidable as the showing of need decreases." *Id*. at *4 (internal quotation marks and citations omitted); *see also Viet. Veterans of Am. v. CIA*, No. 09-cv-0037 CW (JSC), 2011 U.S. Dist. LEXIS 114870, at *9 (N.D. Cal. Oct. 5, 2011) ("[t]he rules of discovery are rooted in

[4] This brief primarily addresses the production of OUS regulatory documents, as Defendants believe a geographic limitation is particularly needed for that category of documents. Defendants have endeavored to produce relevant design and testing documents regardless of whether those documents existed outside the United States, and to produce relevant manufacturing documents for lots identified with a particular plaintiff's claims, including documents located outside the U.S.

proportionality and reasonableness"); *BG Real Estate Servs., Inc. v. Am. Equity Ins. Co.*, No. 04-3408, 2005 U.S. Dist. LEXIS 10330, at *8 (E.D. La. May 18, 2005) (discovery is not a "blank check"; it "requires balancing and imposes on the court the obligation to rein in overly broad, potentially abusive discovery").

Here, plaintiffs have already exceeded the outer limits of permissible discovery with respect to foreign documents. Ethicon has produced, at significant expense, millions of pages of OUS materials requested by plaintiffs in this litigation. Those materials are more than sufficient to allow plaintiffs to prepare and try their case (assuming the materials are even relevant). Forcing Ethicon to provide even more foreign discovery would impose an extreme financial burden on the Company with no meaningful benefit to plaintiffs. Accordingly, Ethicon requests that the Court enter a protective order barring plaintiffs from seeking any further discovery relating to OUS materials. In the alternative, if the Court believes that plaintiffs have a right to even more foreign discovery, Ethicon requests that the Court should impose cost-shifting and require plaintiffs to pay the cost of any future OUS discovery.

I. ETHICON SHOULD NOT BE REQUIRED TO PRODUCE ANY MORE OUS DOCUMENTS.

Rule 26(b)(2) of the Federal Rules of Civil Procedure requires a court to "limit the frequency or extent of discovery otherwise allowed" if it determines that "the burden or expense of the proposed discovery outweighs its likely benefit considering [among other factors] . . . the importance of the discovery in resolving the issues." Fed. R. Civ. P. 26(b)(2)(C)(iii). Similarly, Rule 26(c) allows courts to issue protective orders, on "good cause" shown to prevent an "undue burden or expense" upon the parties by "forbidding the . . . discovery" or "limiting the scope of . . . discovery to certain matters." Fed. R. Civ. P. 26(c)(1)(A) and (D). Ethicon is entitled to a protective order barring further OUS discovery under both of these provisions because: (1) the

additional discovery has marginal – if any – relevance; and (2) any limited benefit would be vastly outweighed by the undue burden and significant expense involved in collecting, reviewing and producing additional foreign documents from dozens of countries across the globe.

A. The Additional OUS Documents Plaintiffs Seek Are Irrelevant To Their Claims.

The additional OUS discovery sought by plaintiffs has no meaningful relevance to plaintiffs' claims in this litigation.

The purpose of the federal discovery rules is to "'focus [discovery] on the actual claims and defenses involved in the action.'" *Collens v. City of New York*, 222 F.R.D. 249, 252 (S.D.N.Y. 2004) (quoting Fed. R. Civ. P. 26(b)(1), Advisory Committee Notes to 2000 Amendments). Thus, while discoverable evidence is not necessarily coextensive with admissible evidence, it is well settled that courts should not permit discovery requests "that amount to nothing more than a 'fishing expedition'" regarding matters "not related to the alleged claims or defenses." *Id*. at 253; *see also Piacenti v. Gen. Motors Corp*., 173 F.R.D. 221, 224 (N.D. III. 1997) (the "legal tenet that relevancy in the discovery context is broader than in the context of admissibility should not be misapplied so as to allow fishing expeditions in discovery"); *Diaz-Padilla v. Bristol Myers Squibb Holding Ltd. Liab. Co*., No. 04-1003 (PG/GAG), 2005 U.S. Dist. LEXIS 5879, at *3-4 (D.P.R. Apr. 4, 2005) (Rule 26 is intended to "confine discovery to the claims and defenses asserted in the pleadings") (internal quotation marks and citation omitted).

Plaintiffs' broad request for additional OUS materials is precisely the type of "fishing expedition" that the discovery rules forbid. As a long line of courts have recognized, foreign regulatory materials and other related documents have no bearing on product-liability cases involving the sale of an allegedly defective product in the United States. *See, e.g.*, *Deviner v. Electrolux Motor AB*, 844 F.2d 769, 771 n.2 (11th Cir. 1988) ("Swedish standards are not

relevant in a U.S. product liability case involving [products] sold in the U.S."); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965 (D. Minn. 2009) ("any discussion of foreign regulatory actions [is]. . . irrelevant to the current litigation" and therefore inadmissible); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (excluding foreign regulatory evidence because "allowing the admission of evidence of foreign regulatory actions, in a case that is governed by domestic law, would likely cause jury confusion"); *Harrison v. Wyeth Labs*, 510 F. Supp. 1, 4-5 (E.D. Pa. 1980) (because each "country has its own legitimate concerns and its own unique needs which must be factored into its process of weighing [a product's] merits. . . fairness to the defendant mandates that defendant's conduct be judged by the standards of the community affected by its actions," not foreign standards), *aff'd*, 676 F.2d 685 (3d Cir. 1982). Thus, the OUS regulatory materials that plaintiffs seek are highly unlikely to lead to the discovery of admissible evidence.

This is particularly so because the information contained in regulatory submissions does not significantly vary from one country to another. (Downs 8/2/13 Decl. ¶¶ 5-11.) As such, the production of regulatory submissions from dozens of additional foreign countries is unlikely to yield more or different information than plaintiffs already have in their possession from Japan, France and Australia.

In previous briefing, plaintiffs relied heavily on Magistrate Judge Stanley's order in the AMS MDL, which rejected AMS's argument that it should not be required to produce any documents from outside the United States. (*See* Pl.'s Mot. to Compel [doc. no. 585] at 8-9 (citing PTO-24, No. 2:12-md-2325 (S.D. W. Va. Oct. 30, 2012)).) In that case, however, Magistrate Judge Stanley was concerned that an absolute bar on foreign discovery would preclude plaintiffs from obtaining adverse event information from foreign countries that would

be relevant to plaintiffs' claims. Magistrate Judge Stanley also noted that e-mails stored on servers outside the U.S. could also include relevant information. These concerns do not apply here because Ethicon has already produced substantial amounts of foreign discovery, including the very adverse event information at issue in the AMS litigation.

As set forth above, Ethicon has already produced millions of pages of OUS documents related to health, safety and marketing issues. Most notably, Ethicon had already produced materials relating to adverse events worldwide. In addition, Ethicon has produced the custodial files of 52 OUS custodians that contain nearly a quarter of a million documents, as well as unique marketing materials for 32 countries and regulatory documents for an additional three. Further, Ethicon has offered to provide a Rule 30(b)(6) witness, Pamela Downs, to testify regarding Ethicon's production of OUS materials and answer any questions plaintiffs might have about relevant, foreign materials that they claim have not yet been produced. Notably, plaintiffs have rejected all of Ethicon's attempts to schedule such a deposition, perhaps because they have no reason to believe that there are undisclosed OUS materials that have any bearing on their claims.

In short, to the extent OUS materials bear any relevance to plaintiffs' claims, they have already been turned over to plaintiffs at Ethicon's substantial expense.

B. Any Alleged Benefit To Plaintiffs From Additional Foreign Discovery Is Vastly Outweighed By The Excessive Cost Of Gathering And Producing Such Materials.

Even if plaintiffs had a legitimate need for additional OUS materials, that need would be vastly outweighed by the substantial and undue burden Ethicon will bear if it is forced to collect, translate and produce regulatory documents from 67 countries across the globe.

Where, as here, the "burden of producing the requested information" outweighs the value of the discovery in light of its "tenuous connection to the issues in th[e] case," a court should

impose a protective order to prevent the discovery from going forward. *Rosenbaum v. Becker & Poliakoff, P.A.*, No. 08-CV-81004-MARRA/JOHNSON, 2010 U.S. Dist. LEXIS 21656, at *23 (S.D. Fla. Feb. 23, 2010); *see also Moore v. Dan Holdings, Inc.*, No. 1:12CV503, 2013 U.S. Dist. LEXIS 61378, at *30-31 (M.D.N.C. Apr. 30, 2013) (refusing to order additional discovery where defendant had already "'produced over 6,000 responsive documents'" because "the burden of any further response to this Request would 'outweigh[] its likely benefit' . . . particularly given the Request's obvious overbreadth") (internal quotation marks and citation omitted); *Defreitas v. Tillinghast*, No. 2:12-CV-00235-JLR, 2013 U.S. Dist. LEXIS 7429, at *9-10 (W.D. Wash. Jan. 17, 2013) (finding good cause for a protective order where the production of the material "would be extremely costly and burdensome," and the "burden outweigh[ed] the likely benefit to [plaintiff] since most of the information . . . [was] unlikely to be relevant"). Thus, where requested discovery may "only marginally enhance the objectives of providing information to the parties or narrowing the issues, the Court must . . . weigh that request with the hardship to the party from whom the discovery is sought." *Priest v. Rotary*, 98 F.R.D. 755, 761 (N.D. Cal. 1983) (internal quotation marks and citation omitted).

Here, there is no question that the burden posed by plaintiffs' overbroad OUS discovery request would be extreme – and that this burden would far outweigh any limited benefit that the discovery would have on plaintiffs' case preparation. As set forth in the attached declaration of Pamela Downs, 67 countries regulate the Ethicon products that are at issue in this litigation. (Downs 8/2/13 Decl. ¶ 3.) Because documents relevant to foreign regulatory issues are generally kept in each respective country and are scattered among various custodians within those countries (*id*. ¶¶ 3, 4, 12), Ethicon would have to search multiple potential sources in dozens of countries in order to respond to plaintiffs' requests. In addition, because foreign regulatory

documents are typically written in the native language of each country, each foreign document would have to be translated before it could be reviewed and produced. (*Id*. ¶ 12.) According to Ms. Downs, it would cost between $500,000 and $1 million to complete this process. (*Id*. ¶ 3, 12.)

In short, the substantial burden of producing additional OUS regulatory materials far outweighs any purported benefit. Accordingly, such discovery should be barred.

II. IF THE COURT ALLOWS ANY ADDITIONAL DISCOVERY, PLAINTIFFS SHOULD BE REQUIRED TO PAY FOR IT.

To the extent the Court allows plaintiffs to pursue additional OUS discovery beyond the millions of pages of materials Ethicon has already produced, it should – at the very least – require them to bear the significant cost of that discovery. As the Supreme Court has explained, "[u]nder th[e] [discovery] rules, the presumption is that the responding party must bear the expense of complying with discovery requests, but he may invoke the district court's discretion . . . to grant orders protecting him from 'undue burden or expense' in doing so, including orders conditioning discovery on the requesting party's payment of the costs of discovery." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 358 (1978). Consistent with this ruling, courts have held that "where the cost of producing documents is very significant, [a district court] has the power to allocate the cost of discovery" to the requesting party "and doing so is fair." *Boeynaems v. LA Fitness Int'l LLC*, 285 F.R.D. 331, 335 (E.D. Pa. 2012) (ordering plaintiffs to pay cost of additional discovery beyond the hundreds of thousands of documents already produced by the defendant; "given the large amount of information [d]efendant has already provided, [p]laintiffs need to assess the value of additional discovery" and decide whether it is truly worth the cost to them); *see also Rowe Entm't, Inc. v. William Morris Agency, Inc.*, 205 F.R.D. 421, 430-32 (S.D.N.Y. 2002) (plaintiffs seeking discovery of defendants' email

archives were required to bear the cost of that discovery because "plaintiffs' demands . . . [were] extremely broad," the "marginal value of searching the e-mails [was] modest at best," and the "costs of the proposed discovery would be substantial by any definition"); *Wiginton v. CB Richard Ellis, Inc*., 229 F.R.D. 568, 577 (N.D. Ill. 2004) (ordering party requesting discovery to bear the majority of discovery costs in light of the limited likelihood that the broad discovery sought would unearth critical information and the high cost of production); *Schweinfurth v. Motorola, Inc.*, No. 1:05CV0024, 2008 U.S. Dist. LEXIS 82772, at *6-7 (N.D. Ohio Sept. 30, 2008) (ordering proposed class action plaintiffs to share cost of the additional discovery they sought where "over 200,000 pages of documents" had already been produced by the defendant and the additional information sought was "immense" in scope).

Any additional foreign discovery in this litigation should be subject to such cost shifting. As set forth above, Ethicon has spent substantial time and money responding to plaintiffs' discovery requests, ultimately resulting in the production of more than 9.5 million pages of documents related to Ethicon's pelvic mesh products. This production included world-wide adverse event reports for the products at issue in this litigation. (Downs 8/2/13 Decl.¶ 13.) In addition, Ethicon produced foreign regulatory documents from Japan, France and Australia, a painstaking process that required extensive communications with individuals in those countries and costly document translation services. (*Id*.) Nonetheless, plaintiffs contend that this overwhelming amount of discovery is not sufficient, and that Ethicon should also be required to locate, collect, review and produce regulatory documents located in approximately 67 countries across the globe. Ethicon estimates that such an undertaking would cost the Company between $500,000 and $1 million to complete. There is simply no justification for saddling Ethicon with

the significant financial burden that would be imposed by this additional, duplicative and irrelevant discovery.[5]

CONCLUSION

For the reasons set forth above, Ethicon respectfully requests that the Court grant a protective order in Ethicon's favor barring any further discovery of Ethicon's OUS materials. In the alternative, Ethicon requests that the Court impose cost-shifting and make plaintiffs pay for any additional OUS discovery.

Dated: August 2, 2013

Respectfully submitted,

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[5] Forcing Ethicon to spend enormous sums of money responding to plaintiffs' burdensome requests for foreign discovery is so grossly unfair that it raises due-process concerns as well. *See* Martin H. Redish & Colleen McNamara, *Back to the Future: Discovery Cost Allocation and Modern Procedural Theory*, 79 Geo. Wash. L. Rev. 773, 807-08 (2011). As the Supreme Court has recognized, deprivation of a property interest, based merely on a plaintiff's ability to make out a facially valid complaint, carries too great a risk of erroneous deprivation to comport with due process. *See, e.g., Connecticut v. Doehr*, 501 U.S. 1, 13-14 (1991) ("[p]ermitting a court to [take away a property interest] merely because the plaintiff believes the defendant is liable, or because the plaintiff can make out a facially valid complaint, would [impermissibly] permit the deprivation of the defendant's property"); *Fuentes v. Shevin*, 407 U.S. 67, 83 (1972) (state laws authorizing the summary seizure of goods or chattels in a person's possession under a writ of replevin violated due process because while "the requirements that a party seeking a writ must first post a bond, allege conclusorily that he is entitled to specific goods . . . they test no more than the strength of the applicant's own belief in his rights"). Here, Ethicon should not be forced to spend millions of dollars responding to unreasonable discovery requests simply because plaintiffs have leveled accusations against the Company and made unreasonable demands for excessive foreign documents.

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CERTIFICATE OF SERVICE

I hereby certify that on August 2, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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